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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,482	09/09/2003	Daryl T. Baldwin	P1974R1	3368

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,482	BALDWIN ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to nucleic acids, vectors, and host cells comprising SEQ ID NO:1, classified in class 536, subclass 23.5, and class 435, subclass 325.

II. Claims 9-11 and 14-17, drawn to polypeptides and compositions comprising SEQ ID NO:2, classified in class 530, subclass 350.

III. Claims 12-17, drawn to antibodies that bind SEQ ID NO;2 and compositions comprising said antibodies, classified in class 530, subclass 387.9.

IV. Claims 14-17, drawn to agonists of the polypeptide of SEQ ID NO:2, classified in class 530, subclass 300.

V. Claims 14-17, drawn to antagonists of the polypeptide of SEQ ID NO:2, classified in class 530, subclass 324.

VI. Claims 18 and 19, drawn to methods of treating immune disorders using the polypeptide of SEQ ID NO:2, classified in class 424, subclass 192.1.

VII. Claims 18 and 19, drawn to methods of treating immune disorders using an agonist of the polypeptide of SEQ ID NO:2, classified in class 514, subclass 2.

VIII. Claims 18, 19, and 27, drawn to methods of treating immune disorders using antagonists of the polypeptide of SEQ ID NO:2, classified in class 514, subclass 8.

IX. Claims 18 and 19, drawn to methods of treating immune disorders using an antibody that binds the polypeptide of SEQ ID NO:2, classified in class 424, subclass 139.1.

X. Claims 20 and 22, drawn to methods of detecting the polypeptide of SEQ ID NO:2 in test samples using antibodies, classified in class 435, subclass 7.92.

XI. Claims 21 and 28-30, drawn to methods of detecting nucleic acid sequences that correspond to SEQ ID NO:1 in test samples, classified in class 435, subclass 6.

XII. Claim 23, drawn to methods of identifying antagonists of the polypeptide of SEQ ID NO:2, classified in class 435, subclass 4.

XIII. Claims 24 and 25, drawn to methods of identifying compounds that inhibit the transcription or translation of nucleic acid sequences encoding the polypeptide of SEQ ID NO:2, classified in class 536, subclass 24.5.

XIV. Claim 26, drawn to a method of identifying agonists of the polypeptide of SEQ ID NO:2, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions (I and (XI, XIII and XIV)), (II and (VI and XII)), (III and (IX and X)), (IV and (VII and XIV)), and (V and (VIII and XII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case all of the products claimed in Groups I-V are disclosed and claimed as being useable in different methods as indicated above. For example, the antibodies of Group III can be used in methods of treatment (Group IX), methods of detection (Group X) or in methods of

purifying the polypeptide of SEQ ID NO:2 (PRO52254). Therefore, they are patentably distinct.

3. Inventions I-V are different products. As such they differ in their primary structure, this difference in structure imbuing the products with unique functional properties. Disclosure of the structure of any one of the inventions of Group I-V does not necessarily anticipate any of the other inventions. For example, a PRO52254 polypeptide may be subject to additional post-translational modifications that are not encoded by the polynucleotide sequence, and the structure of antagonists and agonists of a PRO52254 polypeptide are not immediately envisaged by possession of a PRO52254 polypeptide. These diverse structures give rise to unique functional properties that are not interchangeable and are useful in performing distinct processes. For example, antibodies of the instant invention have the property of binding the polypeptide of SEQ ID NO:2, yet the only molecules bound by the nucleic acids of Group I are other nucleic acids that specifically hybridize with the polynucleotide sequence of SEQ ID NO:1. Agonists and antagonists are completely opposite in their functional properties and potential utilities. As such, all of the products are patentably distinct.

4. Inventions VI-XIV are different methods. As such they recite different process steps such as administering, purifying and developing, require unique ingredients such as polypeptides, antibodies, agonists and antagonists, and achieve divergent goals

including treatment, diagnosis, or identification of agonist and antagonist compounds. Art that anticipates or renders obvious one group would not necessarily anticipate nor render obvious the invention of the other groups. Therefore they are patentably distinct.

5. Inventions (I and (VI-X and XII)), (II and (VII-XI, XIII, and XIV)), (III and (VI-VIII and XI-XIV)), (IV and (VI and VIII-XIII)), and (V and (VI, VII, IX-XI, XIII, and XIV)) are not related as product and process of use. These inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the instant case the different inventions are not taught as being useable together. For example, the nucleic acids of Group I are not useful in performing methods that recite the use of antibodies (Groups IX and X). As such they are patentably distinct.

6. Because these inventions are distinct for the reasons given above, because the literature searches required for Groups I-XIV are not coextensive in that art that anticipates or renders obvious the invention of any one group would not necessarily anticipate or render obvious the inventions of the other groups, and because Groups I-XIV have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species of the claimed invention of Group XI. The species are the identity of the disease being diagnosed by detecting changes in the level of expression of polynucleotides that encode PRO52254. Applicant is required to elect either psoriasis or inflammatory bowel disease as the disease being diagnosed. These species are distinct because they are defined as clinically distinct diseases with unique etiologies, patient populations, standard courses of treatment, and expected therapeutic endpoints.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 21 and 28 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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August 26, 2005

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